

### **REMARKS**

In response to the Office Action mailed April 12, 2005, the Applicants respectfully request reconsideration. To further the prosecution of this Application, the Applicants submit the following remarks, have amended claims, and have canceled claims. The claims as now presented are believed to be in allowable condition.

Claims 1-8 and 20-34 were pending in this Application. By this amendment, claims 2 and 22 are canceled without prejudice. Accordingly, claims 1, 3-8, 20-21, and 23-34 are now pending in this Application. Claims 1, 8, 20, and 29 are independent claims and the remaining claims are dependent claims.

By this response, claims 1, 7, 8, 20 and 29 have been amended. Specifically, claims 1 and 20 have been amended to recite the contents of cancelled claims 2 and 20, respectively. Claim 7 has been amended to correct an antecedent basis issue arising from the amendment made to claim 1. Claims 1, 8, 20 and 29 have also been amended to clarify the nature of the invention. Accordingly, no new matter has been added and the Applicants have not raised any new issues that would require further searching and consideration.

### **Interview Summary**

On September 7, 2005, the Attorneys for the Applicants, Ronald Cahill and Jeffrey Duquette, conducted an interview with Examiner Darwin Erez to discuss the pending independent claims 1, 8, 20, and 29 in the Application along with the art cited in the Office Action. No agreement was reached as to the allowability of the claims in light of the rejections. The Examiner did, however, encourage the Applicants to readdress the motivation to combine the references cited in the § 103 rejections, including the rejection of claim 2 (i.e., now incorporated into claim 1 by amendment). The Attorneys wish to thank the Examiner for his time in this matter.

### **Claim Rejections**

Claims 1, 5, 7 and 20 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,488,690 to Morris et al. Claims 20, 22-24, 25, 26, 29 and 31-34 under 35 U.S.C. § 102(e) were anticipated by U.S. Patent No. 6,358,271 to Egan et al. (Egan '271).

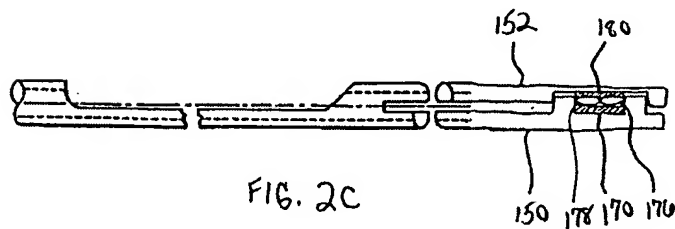
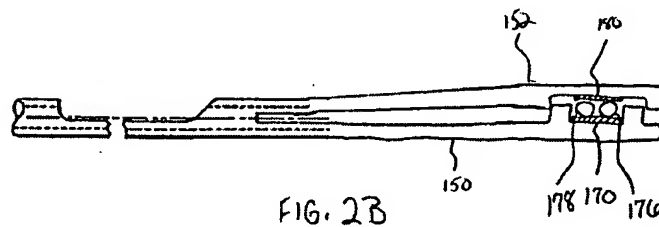
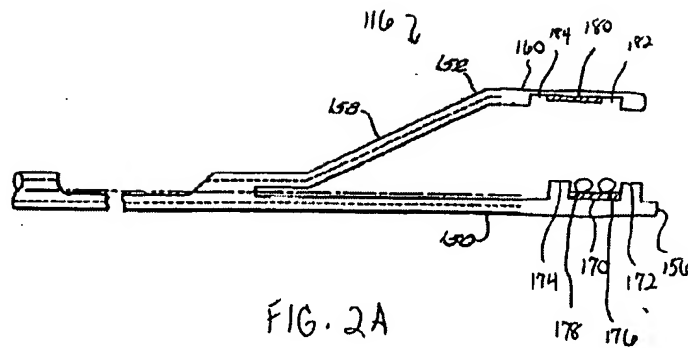
Claims 1, 3, 4 and 28 were rejected under 35 U.S.C. § 103(a) as being unpatentable in light of U.S. Patent No. 6,277,117 to Tetzlaff et al. in view of U.S. Patent No. 6,174,324 B1 to Egan et al. (Egan '324). Claims 1, 2, 8 and 27 were rejected under 35 U.S.C. § 103(a) as being unpatentable in light of U.S. Patent No. 5,342,359 to Rydell in view of U.S. Patent No. 6,174,324 B1 to Egan et al. (Egan '324). Claim 6 was rejected under 35 U.S.C. § 103(a) as being unpatentable in light of U.S. Patent No. 6,488,690 to Morris et al. in view of U.S. Patent No. 4,052,988 to Doddi et al. (Egan '324). Claims 21 and 30 were rejected under 35 U.S.C. § 103(a) as being unpatentable in light of U.S. Patent No. 6,358,271 to Egan et al. (Egan '271) in view of U.S. Patent No. 5,342,359 to Rydell.

The Applicants respectfully disagree with these contentions and asserts that the present claims, are not anticipated by any disclosure in the Morris, Egan '271, Tetzlaff, Egan '324, Rydell, or Doddi references, either alone or in combination.

#### **Applicants' Invention**

The present invention relates to systems, devices and methods for welding lengths of suture to create a fixed attachment between lengths of suture without tying knots. In general, the present invention provides a suture welding device having a suture contacting element with at least one electrode, and coupled to an energy source so that energy can be delivered to first and second lengths of suture in a manner that allows the lengths of suture to be welded to each other. Additionally, as shown in FIGS. 2A-2C (reproduced below), the suture welding device can have pods 172, 174 to restrain the sutures within the grasper 116.

In use, the suture grasper 116 is moved from an open position (FIG. 2A), to an intermediate position (FIG. 2B), and finally to a closed position (FIG. 2C). When the suture grasper 116 is fully closed and two lengths of suture 176, 178 are tightly held within the grasper 116, the lengths of suture 176, 178 can be deformed due to pressure applied to them by the electrodes 170, 180.



**Rejections under 35 U.S.C. § 102(e)**

**Rejections of Applicants' Claims 1, 5, 7, and 20 as Being Anticipated by Morris**

Claims 1, 5, 7, and 20 have been rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,488,690 to Morris et al. However, Morris does not disclose or suggest every element of the Applicants' independent claims 1 and 20.

**The Disclosure of the Morris Reference**

Morris discloses a hand-held instrument for coagulating suture knots. [Abstract.] Specifically, Morris teaches a heating element 108 which is formed into a fork-shaped knot retaining feature [Col. 3, lns. 30-36] or as a cup-shaped recess 202 [Col. 3, lns. 42-43]. In use, a suture 112 is guided from one side of the wound to the other to form a loop 114. Once the loop 114 is formed, a slider-type knot 110 is pushed down onto the suture 112 such that the loop 114 is tightened. [Id.] The heating element 108 is then activated, and simultaneously seals the knot 110 and cuts the end of the looped suture 112. [Id.]

**Morris Does not Disclose the Recitations of Applicants' Claims 1, 5, 7 and 20**

The Applicants' independent claim 1 recites a suture welding system that includes an electrosurgical energy source configured to generate radio frequency waves, first and second lengths of suture, and a suture welding device having a suture contacting element located on a working end wherein provision of *radio frequency* energy by a first electrode to the first and second lengths of suture welds the first and second lengths of suture into a fixed attachment.

As indicated above, Morris discloses a heating element used to heat and seal a suture knot. While Morris discloses that "the device may be modified to make alternative use of ultrasonic energy," Morris does not teach or suggest "provision of *radio frequency* energy by the first electrode to the first and second lengths of suture welds the first and second lengths of suture into a fixed attachment" as claimed by the Applicants.

The Applicants' independent claim 20 relates to a method for welding a first length of suture to a second length of suture to create a fixed attachment therebetween. As part of the method, claim 20 recites providing an electrosurgical energy source and providing a suture welding device having a working end and a suture contacting element disposed on the working end, the suture contacting element having two opposing faces *having a variable gap therebetween*, each face having an electrode disposed thereon.

As indicated above, Morris discloses a heating element which is formed into a fork-shaped knot retaining feature that *enables a slider-type knot 110 to be pushed down* onto one of a pair of suture materials to tighten a loop 114. The heating element 108 is then activated,

simultaneously sealing the knot 110, and cutting the end of the looped suture 112. In Morris, therefore, the knot must be formed within the heating element, as opposed to the heating element having movable ends that can grasp or clamp around a knot. As a result, Morris does not disclose or suggest the fork-shaped knot retaining feature of the heating element as “having two opposing faces *having a variable gap therebetween*” as claimed by the Applicants.

For the reasons stated above, because Morris does not teach or suggest every element of the Applicants’ independent claims 1 and 20, the claims are allowable over Morris. Accordingly, the rejection of these claims should be withdrawn and the claims should be allowed to issue. Claims 5 and 7, which depend on claim 1, should also be allowed to issue as depending upon allowable independent claims (i.e., for at least the reasons presented). Reconsideration of the rejection is respectfully requested.

**Rejections of Applicants’ Claims 20, 23-24, 25, 26, 29, and 31-34 as Being Anticipated by Egan ‘271**

Claims 20, 23-24, 25, 26, 29, and 31-34 have been rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,358,271 of Egan et al. (Egan ‘271). However, Egan ‘271 does not disclose or suggest every element of the Applicants’ independent claims 20 and 29.

**The Disclosure of the Egan ‘271 Reference**

Egan ‘271 discloses an ultrasonically welded loop of elongated material, such as a surgical suture, and an apparatus for making the same. [Abstract.] Specifically, Egan ‘271 teaches a first member 30 which is capable of vibrating and delivering mechanical energy at ultrasonic frequencies, and which moves relative to a second member 32 such that a gap is formed between the members to hold the segments of the loop to be joined together. [Col. 8, lns. 53-67.] The first and second members 30, 32 each have respective suture-contacting surfaces 30A, 32A which are contoured to promote acoustic coupling between the suture segments to be joined. [Col. 9, lns. 1-4.]

**Egan Does not Disclose the Limitations of Applicants' Claims 20, 23-24, 25, 26, 29, and 31-34**

The Applicants' claim 20 recites a method for welding a first length of suture to a second length of suture to create a fixed attachment therebetween, comprising providing an electrosurgical energy source, providing a suture welding device having a *first electrode electrically coupled to the electrosurgical energy source* and disposed on the suture contacting element for providing electrical energy to the first and second lengths of suture and a *second electrode electrically coupled to the electrosurgical energy source* and disposable proximate to the suture welding site for providing a return electrical energy path to the electrosurgical energy source.

Also, the Applicants' claim 29 recites a suture welding that includes, in part, an electrosurgical energy source, *a first electrode electrically coupled to the electrosurgical energy source* and disposed on a suture contacting element for providing electrical energy to first and second lengths of suture, and a *second electrode electrically coupled to the electrosurgical energy source* and disposable proximate to the suture welding site *for providing a return electrical energy path to the electrosurgical energy source*.

As noted above, Egan '271 relates to an apparatus for welding surgical suture that includes a first member 30 that delivers mechanical energy at ultrasonic frequencies to suture segments and a second member 32. Egan '271, however, does not disclose the second member 32 as being a *second electrode electrically coupled to an electrosurgical energy source* as claimed by the Applicants in independent claims 20 and 29. The second member 32 in Egan '271 merely holds or contains suture segments during operation of the apparatus. For example, as shown in FIGS. 10A – 17B of Egan '271, the second member 32 is configured as a support for the suture segments 16, 18. The suture-contacting surface 32A of the second member 32 cooperates with the suture-contacting surface 30A of the first member 30 to hold the suture segments 16, 18 together in order to promote acoustic coupling between the suture segments. There is no disclosure in Egan '271 of the second member 32 being a second electrode *electrically coupled to an electrosurgical energy source for providing a return electrical energy path to the electrosurgical energy source* as claimed by the Applicants in independent claims 20 and 29.

In the Office Action, the Examiner states that Egan '271 discloses employing "electrical arc discharge" to weld sutures together. The Examiner further states that "[e]lectrical arc discharge is when an electrical charge moves from one electrode through the air to a second electrode. Electrical arc discharge, therefore, requires two electrodes." Assuming that, with such disclosure, the second member 32 of Egan '271 could be considered as an electrode (e.g., such as the second electrode of the Applicants' claims 20 and 29), Egan '271 does not disclose or suggest the second member 32 "electrically coupled to the electrosurgical energy source and disposable proximate to the suture welding site for providing a return electrical energy path to the electrosurgical energy source", as claimed by the Applicants.

For the reasons stated above, because Egan '271 does not teach or suggest every element of the Applicants' independent claims 20 and 29, the claims are allowable over Egan '271. Accordingly, the rejection of these claims should be withdrawn and the claims should be allowed to issue. Claims 23-24, 25 and 26, which depend on claim 20, and claims 31-34 which depend on claim 29 should also be allowed to issue as depending upon allowable independent claims (i.e., for at least the reasons presented). Reconsideration of the rejection is respectfully requested.

**Rejections under 35 U.S.C. § 103**

**Rejections of Applicants' Claims 1, 3, 4, and 28 as Being Unpatentable in Light of Tetzlaff in view of Egan '324**

Claims 1, 3, 4, and 28 have been rejected under 35 U.S.C. § 103(a) as being unpatentable in light of U.S. Patent No. 6,277,117 to Tetzlaff et al. in view of U.S. Patent No. 6,174,324 B1 to Egan et al. (Egan '324). However, the Examiner has not established a *prima facie* case of obviousness because the Examiner has not shown any motivation to combine Tetzlaff with Egan '324 and because neither Tetzlaff nor Egan '324, alone or in combination, teach or suggest all of the elements of the Applicants' independent claim 1.

**The Disclosure of the Tetzlaff Reference**

Tetzlaff discloses bipolar forceps having a disposable electrode assembly for sealing, cauterizing, coagulating/desiccating and/or cutting vessels and vascular tissue. [Col. 1, Ins. 6-

10.] The electrode assembly includes a housing which is removably engageable with the mechanical forceps and a pair of electrodes which are attachable to a distal end of the housing, and which reside in opposing relation relative to one another. [Col. 2, lns. 34-41.]

**The Disclosure of the Egan '324 Reference**

Egan '324 discloses a fastener which combines several functions in a single- or multiple-piece suture retaining device. That is, the fastener guides one or more suture strands into the device, and retains the suture strands in a desired orientation within the device so that applied energy effects bonding of the strands to each other and/or to the suture retaining device. [Col. 3, lns. 37-44.] The energy is applied to the external surface of the device by an ultrasonic weld horn, or a source of laser or thermal energy. [Col. 5, lns. 7-11.]

**The Examiner has not Established a Prima Facie Case of Obviousness with Respect to his Rejections of Applicants' Claims 1, 3, 4, and 28 as Being Unpatentable in Light of Tetzlaff in view of Egan '324**

As noted above, the Applicants' independent claim 1 recites a suture welding system that includes an electrosurgical energy source *configured to generate radio frequency waves*, first and second lengths of suture, and a suture welding device having a suture contacting element located on a working end wherein provision of *radio frequency* energy by a first electrode to the first and second lengths of suture welds the first and second lengths of suture into a fixed attachment.

MPEP § 2142 states:

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations... The initial burden is on the Examiner to provide some suggestion of the desirability of doing what the inventor has done.

As noted above, Tetzlaff discloses a device which is used for sealing, cauterizing, coagulating/desiccating and/or cutting vessels and vascular tissue, and Egan '324 discloses a fastener which uses ultrasonic energy to bond one or more suture strands to each other and/or to



the suture retaining device. As the Examiner acknowledged, *Tetzlaff is used for cauterizing human tissue*. However, contrary to the assertion of the Examiner, *nowhere does Tetzlaff suggest that its device can be used in welding suture*. Given that human tissue and suture are two vastly different materials and the motivations of the references (i.e., cauterizing versus material welding) are vastly different as well, there would be no motivation to combine Tetzlaff with Egan '324.

Further, as indicated by Tetzlaff and Egan '324, the state of the art at the time of Applicants' invention was to either to use ultrasonic energy to combine sutures (Egan '324) or use an electrode assembly for cauterizing human tissue (Tetzlaff). Neither reference teaches or suggests "an electrosurgical energy source *configured to generate radio frequency waves*" as claimed by the Applicants in claim 1. Furthermore, neither reference teaches or suggests the provision of *radio frequency* energy by the first electrode to first and second lengths of suture to weld the first and second lengths of suture into a fixed attachment, as claimed by the Applicants in claim 1.

Because the Examiner has not shown any motivation to combine Tetzlaff with Egan '324 and because neither Egan '324 nor Tetzlaff, alone or in combination, teach or suggest all of the elements of the Applicants' independent claim 1, the Examiner has not met the basic requirements for establishing a *prima facie* case of obviousness. Accordingly, the rejection of the claim 1 should be withdrawn and the claim allowed to issue. Claims 3, 4, and 28, which depend on claim 1, should also be allowed to issue as depending upon allowable independent claims (i.e., for at least the reasons presented). Reconsideration of the rejection is respectfully requested.

**Rejections of Applicants' Claims 1, 8, and 27 as Being Unpatentable by Rydell in view of Egan '324**

Claims 1, 8, and 27 have been rejected under 35 U.S.C. § 103(a) as being unpatentable in light of U.S. Patent No. 5,342,359 to Rydell in view of U.S. Patent No. 6,174,324 B1 to Egan et al. (Egan '324). However, the Examiner has not established a *prima facie* case of obviousness with respect to claims 1 and 8 because the Examiner has not shown any motivation to combine Rydell with Egan '324.

**The Disclosure of Rydell**

Rydell discloses a device to cauterize tissue having three concentric tubes, wherein the outer tube is generally rigid, the central tube is an electrically conductive metal in communication with an energy source, and the inner tube is electrically non-conductive. [Abstract.] The distal end of the central tube extends beyond the distal end of the outer tube and functions as an electrode and first jaw of the coagulation instrument. [Id.] The inner tube, which is translationally movable by an operator, has extending therethrough (within its lumen) a conductive lead whose distal end protrudes distally therefrom and is configured at its distal end to function as an opposing second jaw to the first jaw. [Id.] When the inner tube is moved translationally, the second electrode jaw is forced towards the first electrode jaw to bring the jaws into contact with each other. [Id.] Thereafter, when current is introduced to the conductive lead and to the central tube, the resulting electrode jaws can cauterize tissue at the treatment site when such tissue is grasped within the jaws.

**The Examiner has not Established a Prima Facie Case of Obviousness with Respect to his Rejections of Applicants' Claims 1, 8, and 27 as Being Unpatentable in Light of Rydell in view of Egan '324**

As noted above, the Applicants' independent claims 1 and 8 each recite, in part, a suture welding system that includes an electrosurgical energy source, first and second lengths of suture, and a suture welding device having a suture contacting element located on a working end, a first electrode electrically coupled to the electrosurgical energy source and disposed on the suture contacting element for providing energy to the first and second lengths of suture, and a second electrode electrically coupled to the electrosurgical energy source and disposable proximate to the suture welding site for providing a return electrical energy path to the electrosurgical energy source.

Rydell discloses a device to *cauterize tissue* when such tissue is grasped within the electrode jaws, and Egan '324 discloses a fastener which uses *ultrasonic energy* to bond one or more suture strands to each other and/or to the suture retaining device. The Examiner acknowledged, *Rydell is used for welding body tissue*. However, contrary to the assertion of the Examiner, *nowhere does Rydell suggest that its device is capable of welding suture*. Given that

human tissue and suture are two vastly different materials, and the motivations of the references (i.e., cauterizing versus welding) are vastly different as well, there would be no motivation to combine Rydell with Egan '324.

Because the Examiner has not shown any motivation to combine Rydell with Egan '324 with respect to the Applicants' independent claims 1 and 8, the Examiner has not met the basic requirements for establishing a *prima facie* case of obviousness. Accordingly, the rejection of claims 1 and 8 should be withdrawn and the claim allowed to issue. Also claim 27, which depends on claim 1, should also be allowed to issue as depending upon an allowable independent claim (i.e., for at least the reasons presented). Reconsideration of the rejection is respectfully requested.

**Rejection of Applicants' Claim 6 as Being Unpatentable in Light of Morris in view of Doddi**

Claim 6 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,488,690 to Morris in view of U.S. Patent No. 4,052,988 to Doddi et al. Specifically, the Examiner stated:

Morris does not disclose making suture out of polydioxanone, but Doddi teaches that one ought to make suture for use in the body out of polydioxanone because it has many desirable properties, including strength, smoothness, and pliability. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to make Morris' suture out of polydioxanone because this material has many surgically desirable properties such as tensile strength and pliability, as taught by Doddi.

The Applicants disagree with the Examiner's rejection.

**Morris in view of Doddi Does not Disclose the Recitations of Applicants' Claim 6**

Applicants' claim 6 recites first and second lengths of suture that are made out of polydioxanone.

In no way does Morris, either alone or in combination with Doddi, teach or suggest the recitations of Applicants' claim 6. As noted above, Morris teaches a hand-held instrument for *coagulating suture knots*. [Abstract; Col. 2, lns. 26-30.] Nowhere does Morris teach using electrodes, as Morris *heat-seals the suture knots*. [Id.] While Doddi discloses synthetic

absorbable sutures and other surgical devices that are prepared from polymers of p-dioxanone and 1,4-dioxepan-2-one, and alkyl substituted derivatives thereof, *nowhere does Doddi disclose the welding of said sutures*. [Abstract.] Accordingly, even if Morris and Doddi could be combined, the combination does not disclose all of the features of Applicants' claim 6.

Further, there is no motivation to combine the Morris and Doddi references. The heating element in Morris is not capable of *welding* any suture material, let alone, polydioxanone. Further, just because polydioxanone sutures are known does not mean that they can be welded. In fact, an express goal of the claimed invention, the first suture welding device of its type, is to employ radio frequency waves in order to facilitate the welding of polydioxanone sutures. Accordingly, Applicants' claim 6 is allowable over Morris in view of Doddi.

**Rejection of Applicants' Claims 21 and 30 as Being Unpatentable in Light of Egan '271 in view of Rydell**

Claims 21 and 30 have been rejected under 35 U.S.C. § 103(a) as being unpatentable in light of U.S. Patent No. 6,358,271 B1 to Egan et al. (Egan '271) in view of U.S. Patent No. 5,342,359 to Rydell. Specifically, the Examiner stated:

Egan does not disclose radio frequency waves as an energy source, but this is a well known alternative energy source to ultrasonic and electric arc discharge, as demonstrated by Column 1, lines 12-18 of U.S. Patent No. 5,342,359 to Rydell. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to use RF energy instead of electric arc discharge, as it is an alternate and analogous means of applying energy in surgical applications.

Applicants disagree with the Examiner's rejection.

**Egan '271 in view of Rydell Does not Disclose the Recitations of Applicants' Claims 21 and 30**

Applicants' claim 21 recites a method for welding a first length of suture to a second length of suture wherein the electrosurgical energy source generates radio frequency waves. Similarly, Applicants' claim 30 recites a suture welding system wherein the electrosurgical energy source generates radio frequency waves.

In no way do Egan '271 and Rydell, either alone or in combination, teach or

suggest the recitations of Applicants' claims 21 and 30. As noted above, Egan '271 discloses a fused loop of elongated material, such as a surgical suture, made by an *ultrasonic welding technique*, see Abstract, and Rydell discloses a device to *cauterize tissue*. [Abstract.] While Rydell does employ the use of radio frequency energy, *Rydell's purpose is to cauterize tissue, not to weld suture*. Given that human tissue and suture are two vastly different materials and the motivations of the references (i.e., cauterizing versus welding) are vastly different as well, it would be impracticable for one skilled in the art to combine Egan '271 with Rydell. Accordingly, Applicants' claims 21 and 30 are allowable over Egan '271 in view of Rydell.

**CONCLUSION**

In view of the foregoing remarks, this Application should be in condition for allowance. A Notice to this affect is respectfully requested. If the Examiner believes, after this Response, that the Application is not in condition for allowance, the Examiner is respectfully requested to call the Applicants' Representative at the number below.

Applicants hereby petition for any extension of time which is required to maintain the pendency of this case. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 141449.

If the enclosed papers or fees are considered incomplete, the Patent Office is respectfully requested to contact the undersigned collect at (617) 439-2680, in Boston, Massachusetts.

Dated: September 12, 2005

Respectfully submitted,

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